JAN 18 2013

12. 510(k) Summary

Submitter	VasoNova, Inc., a wholly owned subsidiary of Teleflex, Inc. 155 Jefferson Drive, Suite 100 Menlo Park, CA 94025
Name of contact person	Christine Ford, RAC Office phone: 610-378-0131, ext. 3338 Mobile phone: 484-797-7110 Fax: 610-478-3179 Email: christine.ford@teleflex.com
Date summary prepared	December 7, 2012
Device trade or proprietary name	Vascular Positioning System™ (VPS™) G4 Console
Common or usual name	Catheter, Ultrasound, Intravascular
Classification name	Diagnostic intravascular catheter, 21 CFR §870.1200, Class II, product code OBJ
Classification panel	Cardiovascular
Legally marketed device(s) to which equivalence is claimed	K103260 VasoNova Vascular Positioning System™ (VPS™) Console
Device description	The VPS System consists of a VPS Console with tablet display and a VPS Stylet. The VPS G4 Console consists of two key integrated software-driven components: a data acquisition module and an embedded computer with processing capabilities. The data acquisition module within the console transmits and receives ultrasound data while receiving electrical signals from the heart through sensors mounted at the tip of the VPS Stylet. Using signals gathered by the data acquisition module, the graphical user interface provides the user with guidance for tip positioning of central venous access devices. The separately provided VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end of the stylet connects to an extension cable that connects to the VPS Console.
Intended use of the device	The intended use of the VPS Stylet and Console (VPS System) is to quickly and accurately guide market available central catheters to the desired location which is the lower third of the SVC or at the cavo-atrial junction.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristic	Predicate VPS Console	Subject VPS G4 Console
Guidance indicator	Colored icons, waveform data	Colored icons, waveform data
Guidance signal type(s)	ivECG, Doppler ultrasound	ivECG, Doppler ultrasound
Signal Conductor	Two conductor stylet wires (coax cable and ivECG wire)	Two conductor stylet wires (coax cable and ivECG wire)
Acoustic Output	One setting; not controlled by the user	One setting; not controlled by the user
Method of Use	Percutaneous Intravascular	Percutaneous Intravascular

User Interface	PC-based system with keyboard and touch screen	PC-based system connected to a touchscreen tablet display
Software Interface	Custom GUI	Custom GUI

PERFORMANCE TESTS

Characteristic	Standard/Test	Results Summary
Electromagnetic Compatibility	• IEC 60601-1-2: 2007-03 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance: Collateral standard: Electromagnetic compatibility - Requirements and tests	Compliant
Electrical Safety and Acoustic Safety	• IEC 60601-1:1988 (A1:1991 + A2:1995) - Medical electrical equipment - Part 1: General requirements for safety • IEC 60601-1-4: 1996 (A1:1999) /EN 60601-1-4:2000- Medical electrical equipment - Part 1-4: Collateral Standard: Programmable electrical medical systems • IEC 60601-2-37:2001 (A1:2004 + A2:2005) - Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment	Compliant
Software verification and validation	VasoNova Software and Algorithm Verification and Validation testing	Compliant

Conclusions:

The intended use, technological characteristics, method of collecting and interpreting physiological data, and performance of the predicate VasoNova VPS Console and the VPS G4 Console along with testing to voluntary standards and applicable FDA guidance documents provide evidence that the subject VPS G4 console is substantially equivalent to the predicate VPS Console in terms of safety, efficacy, and performance.

The described physical, software, and hardware modifications are enhancements to various aspects of the predicate VPS Console. They do not alter the fundamental scientific technology of the device; they do not alter the method in which physiological data is collected from the patient; they do not alter the method in which physiological data is interpreted by the software algorithm to determine the symbols used to indicate catheter migration through the vasculature and final tip placement. Any differences between the subject VPS G4 Console and the predicate VPS Console do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

JAN 18 2013

Vasonova Inc.
c/o: Christine Ford
Regulatory Affairs Manager
155 Jefferson Drive, Suite 100
Menlo Park, CA 94025

Re: K123813
Trade Name: Vascular Positioning System (VPS™) G4 Console
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: December 7, 2012
Received: December 19, 2012

Dear Ms. Ford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123813

Device Name: Vascular Positioning System (VPS™) G4 Console

Indications For Use:

The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Console is intended for use with the stylet supplied by VasoNova. The Vascular Positioning System consists of a Console and associated power supply and cabling and a stylet. The VPS Console, when used with the VPS Stylet, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the Vascular Positioning System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location. The Vascular Positioning System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients. NOTE: If a steady blue bull's eye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123813